

REMARKS**I. Petition for Extension of Time**

Applicants herewith petition the Commissioner for Patents to extend the time for response to the Office action mailed July 16, 2004 for two months from October 16, 2004 to December 16, 2004. Authorization is given to charge the extension of time fee of \$430.00 (37 C.F.R. §§1.136 and 1.17) to Deposit Account No. 23-1703. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

II. Prosecution History

The grandparent of the subject application is U.S. Patent Application Serial No. 09/077,719 (the "719 application"), filed June 8, 1999, now US 6,369,085 (the "085 patent"), issued April 9, 2002. Claim 1 of the subject application is identical to original claim 1 of the '719 application.

III. The Claimed Invention

The present invention is directed to the magnesium salt of the (-)-enantiomer of omeprazole. As defined in the specification at page 3, line 3-9, the compound of the claimed invention is referred to as the magnesium salt of S-omeprazole trihydrate. However, as used throughout this communication, the expressions "the (-)-enantiomer of omeprazole" and "S-omeprazole" will be used interchangeably.

IV. Claim Rejection – 35 U.S.C. §112

Claim 18 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicants regard as the invention. It is alleged that the expression "gastric acid related condition" is indefinite.

The test for definiteness is whether one skilled in the art would understand the expression when read in light of the specification. Applicants respectfully submit that the person of ordinary skill in the art would not find the expression "gastric acid related condition", as recited in claim 18, to be indefinite.

Specifically, the person of ordinary skill in the art knows that the therapeutic nature of S-omeprazole is directly attributed to its control or inhibition of gastric acid secretion at its source, i.e., the proton pump of the parietal cell. This knowledge is consistent with the disclosure in the specification at page 1, lines 14-20, that S-omeprazole is a known proton pump inhibitor.

Thus, the person of ordinary skill in the art knows that the administration of S-omeprazole is useful in the prevention and treatment of gastric acid related conditions. Moreover, the same expression "gastric acid related condition" was found to be definite in the related grandparent, i.e., the '085 patent. In this regard, the Examiner's attention is directed to claim 12 of the '085 patent.

For all of the foregoing reasons, withdrawal of the § 112 rejection is respectfully requested.

V. Claim Rejections – 35 U.S.C. §103

Claims 1, 2, 14, 17 and 18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lindberg (WO 94/27988) and Bergstrand (WO 96/01623).

The Examiner states that Lindberg, at Example 5 on page 12, and Bergstrand, at Example A on page 34, disclose the magnesium salt of S-omeprazole. The Examiner acknowledges, however, that neither Lindberg nor Bergstrand discloses or suggests the trihydrate of the magnesium salt of S-omeprazole. Therefore, in the absence of some unexpected superior property, the Examiner concludes that the claimed invention would have been obvious to the person of ordinary skill in the art.

Applicants submit that the claimed invention is nonobvious in view of Lindberg and Bergstrand. Example 5 of Lindberg discloses that the magnesium salt of S-omeprazole was obtained as a white powder, whereas Example A of Bergstrand discloses that the magnesium salt of S-omeprazole was obtained as white crystals. Neither reference suggests that another form of magnesium salt of S-omeprazole is possible. Therefore, the cited prior art does not and cannot provide the motivation or incentive as required by 35 U.S.C. §103 to expect or look for another form of magnesium salt of S-omeprazole. Accordingly, at the time the claimed invention was made, the prior art did not offer a reasonable expectation of successfully finding another form of magnesium salt of S-omeprazole.

Accordingly, Applicants respectfully submit that the claimed invention is nonobvious in view of Lindberg and Bergstrand. Withdrawal of the §103 rejections is requested.

VI. Claim Rejections – Double Patenting

Claims 1, 2, 14 and 18 are rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1, 2, 11 and 12 of the '085 patent.


By the express language of the claims, the scope of the claims of the '085 patent is different from the scope of claims 1, 2, 14 and 18 of the subject application. Therefore, withdrawal of the §101 rejection is requested.

CONCLUSION

Applicants submit that pending claims 1, 2, 14, 17 and 18 are in condition for allowance, which action is earnestly solicited. The Assistant Commissioner is hereby authorized to charge Deposit Account No. 23-1703 in the event that any fee is required in connection with this communication.

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Respectfully submitted,



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